# In the United States Court of Federal Claims

# **OFFICE OF SPECIAL MASTERS**

No. 18-0226V Filed: June 7, 2019 UNPUBLISHED

KIMBERLY RAYBORN,

Petitioner,

٧.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Processing Unit (SPU); Findings of Fact; Onset; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Amy A. Senerth, Muller Brazil, LLP, Dresher, PA, for petitioner. Ryan Daniel Pyles, U.S. Department of Justice, Washington, DC, for respondent.

# FACT RULING AND SCHEDULING ORDER - SPECIAL PROCESSING UNIT

**Dorsey**, Chief Special Master:

On February 14, 2018, Kimberly Rayborn ("petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*,<sup>2</sup> (the "Vaccine Act" or "the Act"). Petitioner alleges that she suffered a left shoulder injury related to vaccine administration ("SIRVA") as a result of an influenza ("flu") vaccine she received on September 21, 2016. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

<sup>&</sup>lt;sup>1</sup> The undersigned intends to post this ruling on the United States Court of Federal Claims' website. **This means the ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access. Because this published ruling contains a reasoned explanation for the action in this case, undersigned is required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services).

<sup>&</sup>lt;sup>2</sup> National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

Petitioner now moves for a ruling on the record making a finding of fact that the onset of petitioner's shoulder injury was within 48 hours of receiving the flu vaccination. ECF No. 25, Petitioner's Motion for a Fact Ruling on the Issue of Onset ("Motion"). For the reasons discussed below, the undersigned grants petitioner's Motion and finds that the onset of petitioner's shoulder injury was within 48 hours of her September 21, 2016 flu vaccination.

### I. <u>Procedural History</u>

On February 14, 2018, in addition to the petition, petitioner filed medical records as Exhibits 1-3 and an affidavit as Exhibit 4. (ECF No. 1). On February 20, 2018, petitioner filed the vaccine administration record as Exhibit 5 and, on February 26, 2018, filed a statement of completion. (ECF Nos. 6, 8). Immediately following the March 20, 2018 initial status conference, petitioner filed additional medical records as Exhibits 6 and 7. (ECF No. 10). On April 10, 2018, petitioner filed an amended petition in which the date of vaccination was corrected. (ECF No. 11). Petitioner's second affidavit and a more detailed record of vaccine administration were filed on April 13 and April 23, 2018 as Exhibits 8 and 9. (ECF Nos. 13, 14).

On November 14, 2018, respondent filed the Rule 4(c) Report asserting that petitioner had not demonstrated entitlement to compensation. Respondent's Report (ECF No. 23). Specifically, respondent argued that the record is insufficient to substantiate that the onset of petitioner's left shoulder symptoms began within forty-eight hours of vaccination because "petitioner did not seek care for her alleged injury until . . . almost four months after the vaccination." *Id.* at 3.

On November 20, 2018, the undersigned ordered petitioner to file a detailed affidavit and Motion for a Ruling on the Record regarding onset. See Scheduling Order at 1 (ECF No. 24). Petitioner filed her Motion on January 14, 2019 without an affidavit. (ECF No. 25). Respondent filed his response on March 5, 2019. (ECF No. 26). Thus, petitioner's Motion is now ripe for adjudication.

#### II. Relevant Factual History

On September 21, 2016, petitioner received a flu vaccination in her left arm. Ex. 9. Petitioner's medical history does not appear to be contributory to her claim in this case. See *generally* Ex. 7 at 34-35 (listing petitioner's past medical history and "active problems.").

Approximately 4 months later, on January 18, 2017, petitioner first presented to Nurse Practitioner ("NP") Anne Musgrove at Memorial Southern Coast Family Medicine with complaints of left shoulder pain. Ex. 3 at 4. According to the clinical record, petitioner's pain "began in September on the evening she received her flu vaccine at work." *Id.* It is noted that petitioner initially attempted to treat her shoulder with nonsteroidal anti-inflammatory drugs ("NSAIDs") and sought to alleviate pain through the strategic placement of pillows during the night and limiting weight-bearing activities. *Id.* Despite these measures, petitioner's shoulder pain continued. *Id.* It was also noted

that "abduction of the left arm is limited to approximately 85 [degrees] actively and 94 [degrees] passively. There is some weakness in her left hand, sometimes losing her grip strength." *Id.* The clinical notes reflect "constant 2/10 dull aching with episodes of 6/10 pain with abduction of L[eft] arm." *Id.* NP Musgrove diagnosed petitioner with a vaccine reaction and referred her for magnetic resonance imaging ("MRI"). *Id.* at 5.

On January 22, 2017, petitioner underwent an MRI of her left shoulder. *Id.* at 1-2. The MRI report notes petitioner's "[l]imited range of motion of the shoulder since the fluid [sic] shot." *Id.* at 1. The MRI revealed "some mild thickening of the joint capsule at the axillary recess which can be seen with adhesive capsulitis." *Id.* at 2.

On February 2, 2017, petitioner presented to Dr. Arthur D. Black, an orthopedist. Ex. 6 at 1-2. Petitioner reported left shoulder pain "that started approximately 4 months ago after receiving a flu shot in the same shoulder." *Id.* at 1. Petitioner further reported having had "some relief [of] some of the symptoms with activity modification and anti-inflammatories however they have not completely resolved." *Id.* Petitioner was assessed with "left shoulder bursitis, slow to resolve," and was given a cortisone injection. *Id.* at 2.

Petitioner returned to Dr. Black on March 21, 2017 to follow-up on her left shoulder pain. *Id.* at 3-4. The clinical notes indicate that while the previously administered cortisone injection had initially provided pain relief, petitioner's symptoms were beginning to return. *Id.* at 3. Petitioner was assessed with having left shoulder impingement symptoms and petitioner was prescribed physical therapy. *Id.* at 4.

On April 21, 2017, petition completed a Vaccine Adverse Event Reporting System form ("VAERS Report") indicating "left shoulder pain onset [illegible] injection." Ex. 1 at 2. The date of onset is listed as September 21, 2016. *Id*.

Petitioner participated in 13 sessions of occupational therapy from March 30, 2017 through June 20, 2017. Ex. 2 at 40-68. The outpatient evaluation note states that petitioner "has a history of approximately 6 months of left shoulder pain." *Id.* at 68.

In petitioner's second affidavit, petitioner states that she began experiencing left shoulder pain following her September 21, 2016 flu shot. Ex. 8 at ¶ 3. Petitioner explains that, "[i]n the past with vaccination, I had often experienced some mild soreness typically resolving within a few days." *Id.* Petitioner explained that, unlike the soreness she experienced following previous vaccinations, the pain that followed her September 21, 2016 vaccination persisted. *Id.* Petitioner noted that as "a nurse practitioner and busy mom I continued to just treat supportively. Once I began having limited range of motion as well as continued pain, I knew there was something more wrong." *Id.* 

# III. <u>Discussion</u>

#### a. Applicable Legal Standard

Effective for petitions filed beginning on March 21, 2017, SIRVA is an injury listed on the Vaccine Injury Table ("Table"). See Vaccine Injury Table: Qualifications and aids to interpretation. 42 C.F.R. § 100.3(c)(10). Therefore, the undersigned's findings are informed by the Qualifications and Aids to Interpretation for SIRVA criteria used to evaluate such claims. The criteria are as follows:

A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following: (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection; (ii) Pain occurs within the specified time-frame; (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

*Id.;* see also National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, Notice of Proposed Rulemaking, July 29, 2015 (citing Atanasoff S, Ryan T, Lightfoot R, and Johann-Liang R, 2010, *Shoulder injury related to vaccine administration (SIRVA)*, Vaccine 28(51):8049-8052). The criteria at issue in this case is whether petitioner's pain occurred within the specified time-frame of 48 hours or less after administration of her September 21, 2016 flu vaccination. The undersigned finds that it does.

# b. Evaluation of the Evidence

The parties dispute whether petitioner has satisfied her burden of proof as to the second SIRVA criteria: "[pain occur[ring] within the specified time-frame." To meet this criterion, petitioner must show by preponderant evidence that her left shoulder pain began within 48 hours of her September 21, 2016 flu vaccination. 42 U.S.C. § 300aa–13(a)(1)(A); 42 C.F.R. § 100.3(c)(10). Petitioner has the burden of demonstrating the facts necessary for entitlement to an award by a "preponderance of the evidence." § 300aa-12(a)(1)(A). Under that standard, the existence of a fact must be shown to be "more probable than its nonexistence." *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring). In light of all of the above record evidence and for the reasons described below, the undersigned finds that there is preponderant evidence that the onset of petitioner's alleged shoulder pain occurred within 48 hours of petitioner's September 21, 2016 flu vaccination.

It is undisputed that petitioner was not seen by a healthcare provider until January 18, 2017, almost four months after her September 21, 2016 flu shot. However, the medical records provide preponderant evidence demonstrating that the onset of her shoulder pain began within 48 hours of the administration of the flu vaccine. On the first occasion that petitioner sought treatment for her left shoulder injury, she reported that her shoulder pain "began in September on the evening she received her flu vaccine." Ex. 7 at 10. Moreover, in recounting petitioner's history of shoulder pain, the report

documenting petitioner's January 22, 2017 MRI indicates that she experienced limited range of motion in her left shoulder since the "fluid [sic] shot." *Id.* at 4. Consistent with this timeline is petitioner's February 2, 2017 report to her orthopedist that her shoulder pain "started approximately 4 months ago after receiving a flu shot in the same shoulder." Ex. 6 at 1. Petitioner's subsequent occupational therapy evaluation on March 30, 2017 further corroborates petitioner's claim that her shoulder pain began within 48 hours of the flu vaccination: It is noted that petitioner "has a history of approximately 6 months of left shoulder pain." Ex. 2 at 68. Moreover, petitioner's VAERS Report indicates an onset date of September 21, 2016, the date of petitioner's vaccination.

The undersigned recognizes that some of the aforementioned medical records are imprecise regarding onset (e.g., "approximately 4 months ago"); however, it would be a mistake to overanalyze these notations in search of a precise onset date when these notes were provided as generalizations. The reported timeframe reflected by the record as a whole encompass the 48-hour post-vaccination period. Moreover, it is significant that on January 18, 2017, the first time petitioner sought treatment for her shoulder, she reported that her pain began "on the evening she received the flu vaccine." Ex. 7 at 10.

Additionally, the undersigned finds petitioner's second affidavit explaining her delay in seeking treatment to be reasonable and credible. *See, e.g., Stevens v. Sec'y of Health & Human Servs.*, 90-221V, 1990 WL 608693, \*3 (Cl. Ct. Spec. Mstr. 1990)(noting that clear cogent, and consistent testimony can overcome missing or contradictory medical records). Petitioner indicated that she had previously experienced mild soreness after vaccinations that typically resolved within a few days. Ex. 8 at 1. Petitioner also indicated that, as a nurse and busy mom, she initially sought to treat the pain with ibuprofen and by applying ice. *Id.* at 2. Given that petitioner was noted to have had "some relief [of] symptoms with activity modification and anti-inflammatories," (Ex. 6 at 1) petitioner's decision not to seek immediate attention was reasonable. Further, because petitioner is a nurse, and it is typical for many medical professionals to self-treat, they often wait before seeking formal medical treatment. In the undersigned's experience, petitioner's affidavits and medical records as a whole reflect a pattern of treatment consistent with and similar to many other compensated SIRVA claims.

Based on the record as a whole, the undersigned finds that there is preponderant proof that the onset of petitioner's left shoulder pain occurred within 48 hours of her September 21, 2016 flu vaccination.

#### IV. Conclusion

The undersigned finds, based on the record as a whole, that the onset of petitioner's left shoulder pain was within forty-eight (48) hours of her September 21, 2016 influenza vaccination.

The parties are encouraged to consider an informal resolution of this claim. Petitioner shall file a joint status report by no later than Monday, July 8, 2019,

updating the court on the status of the parties' progress informally resolving this claim.

IT IS SO ORDERED.

s/Nora Beth DorseyNora Beth DorseyChief Special Master